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PATENT

Attorney Docket No.: 8830-23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent application of :
Camilo Anthony Leo Selwyn Colaco :
Serial No.: 10/049,706 : Group Art Unit:
Filed: April 16, 2002 : 1645 :
For: TREHALSOE PRODUCING PROKARYOTIC : Examiner:
CELLS AS VACCINES : Khatol S. Shahnan-Shah

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the office action mailed December 19, 2003. Per the petition and fee submitted herewith, Applicant invokes the benefit of 37 C.F.R. 1.136 to secure a three-month extension of time up to and including April 19, 2004. No further fees are believed due to support the filing of this paper. If an additional fee is due, please charge the same to deposit account 50-0573, and credit any excess to the same account.

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**CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

BY Shanna R. Smith
DATE: 4/16/04

Response to Restriction Requirement

Applicant elects, with traverse, Group II (claims 14-18). Reconsideration of the Restriction Requirement in all aspects is requested in view of the following remarks.

The present claims are restricted into four groups:

Group I (claims 1-13), drawn to a method for producing a vaccine containing an immunogenic determinant, in which the immunogenic determinant is a prokaryotic cell which has been treated under conditions such that an increase in the concentration of trehalose is induced within the cell.

Group II (claims 14-18), drawn to a vaccine containing an immunogenic determinant, in which the immunogenic determinant is a prokaryotic cell or cell residue which contains at least 10mM of trehalose within the cell.

Group III (claims 20-21), drawn to a method of treating an animal with the vaccine of claim 14.

Group IV (claim 22), drawn to a modified prokaryotic cell which has been modified such that trehalose is constitutively expressed within the cell as it grows.

The claims of Groups I, II, III and IV relate, respectively, to a process for making a vaccine, to the vaccine made by the claimed process, to a method of using the claimed vaccine and to a modified cell for use in the above methods and composition. For the reasons discussed below, the claims of Groups I, II, III and IV have unity of invention and are related by a technical feature which makes a contribution over the prior art, and should be rejoined for examination on the merits.

The present application represents the U.S. national stage of a PCT application, as filed under 35 U.S.C. § 371. MPEP § 1893.03 states that prosecution of an international application which enters the national stage in the U.S. under 35 U.S.C. § 371(c) "proceeds in

the same manner as for a domestic application with the exceptions that . . . (B) unity of invention proceeds as under 37 C.F.R. § 1.475," which is governed by PCT Rule 13.

Unity of invention under PCT Rule 13 is satisfied when there is a technical relationship among those inventions defined by the claims which involves "one or more of the same or corresponding special technical features." This unifying special technical feature is that which defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. PCT Rule 13.2 and the PCT Administrative Instructions, Annex B, Part 1(b).

Where a single patent application contain claims of different categories, the claims have unity of invention when all claims contain a special technical feature, and the claimed manufacturing process is specifically adapted to produce the claimed product. A process is "specifically adapted" for the manufacture of a claimed product when that process inherently results in the product. PCT Administrative Instructions, Annex B, Part 1(e)(i). According to the PCT Administrative Instructions, Annex B, Part 1(e)(iii), "[t]he words 'specifically adapted' are not intended to imply that the product could not also be manufactured by a different process." Thus, the Examiner need only consider whether claims of different categories contain the same or corresponding special technical feature, and whether the claimed process of manufacture inherently produces the claimed product.

With regard to the present invention, the special technical feature is the immunogenic determinant, which comprises a prokaryotic cell which has been treated in order to increase the amount of trehalose present within the cell, this resulting in the cell being more immunogenic. All claims in groups I, II, III and IV contain this feature. The modified prokaryotic cell is more immunogenic than an unmodified prokaryotic cell and accordingly the present invention is based on the fundamental technical observation that prokaryotic cells which are stabilized with trehalose are more immunogenic than fresh, live cells.

The document cited by the Examiner, US Patent No 5,422,254 to Londenborough et al. teaches of the transformation of yeast cells in order to result in an increase in the production of trehalose. In particular, Londenborough et al. teaches of the transformation of strains of distillers yeast with structural genes relating to short and long chains of purified

trehalose synthase (column 4, lines 22 to 25) and further to the transformation of the isolated genes to higher plants (column 4, line 45) and crop plants (column 4, line 68) in order to increase trehalose content and confer associated improvements such as resistance to frost and drought and other associated improvements in plant properties.

Londesborough et al. mentions “other host cells” (column 4, line 6) and “organisms (such as yeast, other fungus or higher eukaryotes)” (column 5, lines 15 to 17). There is no teaching in Londesborough et al. that the host cell which is modified can be a prokaryotic cell. It cannot be merely assumed that the man skilled in the art can extend the teaching of Londesborough et al. to the transformation of prokaryotic cells. Even if such a transformation was taught by Londesborough et al., then there would be no disclosure, indication or suggestion that the modified host cell (whether it be prokaryotic or otherwise) would necessarily be more immunogenic than the equivalent host cell which has not been stabilized in trehalose.

It is further submitted that the invention disclosed in Londesborough et al. serves to improve trehalose production within yeast in order to obtain improvements in the yeast and other *eukaryotic* cells which are known to be derived from trehalose production. These improvements are described throughout Londesborough et al. as improvements in trehalose yield within yeast for industrial scale production of trehalose (column 4, line 30), improved ethanol yield from distiller’s yeast (column 4, line 25) and improvement of plant resistance to frost and dehydration (column 4, lines 45 to 56). The present invention however discloses a novel observation in relation to the production of trehalose in a *prokaryotic* cell, namely the that a cell in which trehalose production can induce an improved immune response.

It is therefore respectfully submitted that the technical feature which underpins and links the inventions of Groups I-IV is the use of a trehalose stabilized modified prokaryotic cell, which confers improved immunogenicity over a non-modified cell. Such a technical feature is not disclosed in the prior art, and in particular the document of Londesborough et al. and accordingly the provisions of PCT Rule 13.2 are met as the present invention as claimed provides a distinct contribution over the art.

Because all claims of Groups I, II, III and IV have the same special technical feature, and the claimed product in Group II is inherently made by the claimed Group I process, all pending claims have unity of invention. Applicant requests that the Group I, II, III and IV claims be rejoined for examination on the merits.

Respectfully submitted

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